

Claims

- 5 1. An oral dosage form comprising a first composition and a second composition, each composition comprising a pharmaceutically acceptable weak base ('the drug') and a pharmaceutically acceptable carrier therefor, wherein the first and second compositions are arranged to release drug at differing release rates on administration such that the rate of release of the drug from the dosage form is substantially independent of pH.
- 10 2. An oral dosage form according to claim 1, wherein the release rate of the drug from the first composition is substantially greater than from the second composition.
- 15 3. An oral dosage form according to claim 1 or claim 2, wherein the first composition is an immediate release composition.
4. An oral dosage form according to any preceding claim, wherein the second composition is a modified release composition.
- 20 5. An oral dosage form according to claim 1, wherein the rate of release of the first and/or second composition(s) from the dosage form is a modified release.
- 25 6. An oral dosage form according to claim 5, comprising a third composition comprising substantially no drug substance.
7. An oral dosage form according to claim 6, wherein said third composition is an enteric composition.
- 30 8. An oral dosage form according to claim 7, wherein said third composition comprises one or more openings extending substantially completely

through the third composition, thereby exposing at least one surface of the first and/or second composition(s) to the environment of use.

9. An oral dosage form according to claim 1, wherein the first composition is
5 arranged so that in use it releases substantially all of the pharmaceutically acceptable weak base in the stomach.

10. An oral dosage form according to claim 1, wherein the second composition
10 is arranged so that in use it releases substantially all of the pharmaceutically acceptable weak base in the small intestine.

11. An oral dosage form according to claim 1, which dosage form is arranged to
15 release the pharmaceutically acceptable weak base such that the mean maximum plasma level concentration ("C_{max}") value of the drug is maintained substantially independent of food during use.

12. An oral dosage form according to claim 1, which dosage form is arranged
20 to release the pharmaceutically acceptable weak base such that the mean area under the plasma concentration versus time curve over the dosing interval at steady state ("AUC") is maintained substantially independent of food during use.

13. An oral dosage form according to claim 1, which dosage form is arranged to
25 release the pharmaceutically acceptable weak base so that both the C_{max} value and AUC observed on administration are maintained substantially independent of food during use.

14. An oral dosage form according to claim 1, comprising,
30 (i) an erodable core, which core comprises a pharmaceutically acceptable weak base and a pharmaceutically acceptable carrier therefor; and
(ii) an erodable coating around said core, which coating comprises one or more openings extending substantially completely through said coating but not penetrating said core and communicating from the environment of use

to said core, wherein release of pharmaceutically acceptable weak base from the erodable core occurs substantially through the said opening(s) and through erosion of said erodable coating under pre-determined pH conditions;

5 wherein the core comprises a first composition and a second composition, each composition comprising a pharmaceutically acceptable weak base ('the drug') and a pharmaceutically acceptable carrier therefor, wherein the first and second compositions are arranged to release drug at differing release rates on administration such that the rate of release of the drug from the dosage form is substantially independent of pH.

10 15. An oral dosage form according to claim 14, wherein the first composition is formulated so that it provides immediate release of the pharmaceutically acceptable weak base on contact with aqueous media.

15 16. An oral dosage form according to claim 14 or claim 15, wherein the second composition is formulated so that it provides modified release of a pharmaceutically acceptable weak base on contact with aqueous media.

20 17. An oral dosage form according to claim 1, wherein the dosage form is a tablet form.

18. An oral dosage form according to any preceding claim, in which the pharmaceutically acceptable weak base is 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof.

25 19. A process for preparing an oral dosage form comprising a first composition and a second composition, each composition comprising a pharmaceutically acceptable weak base ('the drug') and a pharmaceutically acceptable carrier therefor, according to claim 1, which process comprises at least the steps of sequentially or simultaneously:

30 (i) formulating the drug into the first composition; and

(ii) formulating the drug into the second composition;
whereby the first and second compositions are formulated to release drug
at differing release rates on administration such that the rate of release of
the drug from the dosage form is substantially independent of pH.

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20. A process for the preparation of an oral dosage form comprising an
erodable core, which core comprises a pharmaceutically acceptable weak
base and a pharmaceutically acceptable carrier therefor; and an erodable
coating around said core, which coating comprises one or more openings
extending substantially completely through said coating but not penetrating
said core and communicating from the environment of use to said core,
10 wherein release of pharmaceutically acceptable weak base from the
erodable core occurs substantially through the said opening(s) and through
erosion of said erodable coating under pre-determined pH conditions,
15 according to claim 14, which process comprises:
(a) formulating an erodable core comprising the pharmaceutically
acceptable weak base and a pharmaceutically acceptable carrier therefor;
(b) coating the said core with an erodable coating; and
(c) creating one or more openings in the coating, said openings extending
20 substantially completely through said coating but not penetrating said core
and communicating from the environment of use to said core.

21. A method for the treatment and/or prophylaxis of the Disorders of the
Invention in a human or non-human mammal, which method comprises
25 administering an oral dosage form according to claim 1, comprising
Compound A or a pharmaceutically acceptable salt or solvate thereof, to a
human or non-human mammal in need thereof.

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